



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1043]

### Exemption of Certain Categories of Biological Products from Certain Reporting Requirements under the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is proposing to exempt certain categories of biological products from certain reporting requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Specifically, each person who registers with FDA with regard to a drug is required to report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution; however, certain biological products or categories of biological products may be exempted by order from these reporting requirements if FDA determines that applying such reporting requirements is not necessary to protect the public health. FDA is proposing to exempt the two categories of biological products from these reporting requirements because the Agency has determined that applying such requirements is not necessary to protect the public health.

**DATES:** Submit either electronic or written comments on the proposed order by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Please see section IV of this document for the proposed effective date when the exemptions apply and for the proposed effective date of a final order based on this proposed order.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

*REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2021-N-1043 for “Exemption of Certain Categories of Biological Products from Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Sana F. Hussain, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

I. Background--Reporting Requirements Under Section 510(j)(3) of the FD&C Act

On March 27, 2020, the CARES Act (Pub. L. 116-136) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019. In addition, the CARES Act included authorities to enhance FDA’s ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA’s visibility into drug supply chains.

Section 3112(e) of the CARES Act added new paragraph (j)(3) to section 510 of the FD&C Act (21 U.S.C. 360(j)(3)), which requires that each person who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. FDA anticipates that these reporting requirements in section 510(j)(3)(A) of the FD&C Act will enhance FDA’s ability to anticipate and react expeditiously to drug shortages by enabling the Agency to quickly identify all manufacturing sites impacted, analyze potential bottlenecks, and develop options to remediate shortage risks to the product supply chain.

Under section 510(j)(3)(B) of the FD&C Act, FDA may exempt certain biological products or categories of biological products regulated under section 351 of the Public Health Service Act (42 U.S.C. 262) from some or all of the reporting requirements under section

510(j)(3)(A) of the FD&C Act, if FDA determines that applying such reporting requirements is not necessary to protect the public health.

## II. Categories of Biological Products Proposed for Exemption

FDA is proposing to exempt the following two categories of biological products from all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act because FDA has determined that applying such reporting requirements is not necessary to protect the public health:

- Blood and blood components for transfusion; and
- Cell and gene therapy products, where one lot treats a single patient.

### 1. Blood and Blood Components for Transfusion

In accordance with section 510(j)(3)(B) of the FD&C Act, FDA is proposing to exempt blood and blood components for transfusion from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Generally, registered blood establishments are inspected on a biennial basis by the Agency. There are approximately 1,900 registered blood establishments that manufacture blood and blood components for transfusion, all located in the United States, except a small number of United States military blood establishments that are located internationally in order to provide blood and blood components to United States military personnel onsite when needed. The supply chains for blood and blood components for transfusion are well-established and well-understood based on the nature of the products; namely, blood is collected from human donors

via venipuncture, separated into components (if applicable), and stored at specified temperatures and under the complete control of each blood establishment. Additionally, supply chains for blood and blood components for transfusion are controlled and secure from initial donation to final product delivery to the transfusion site and, generally, do not involve wholesale distributors, brokers, or other intermediaries. Further, many registered blood establishments voluntarily submit the amount of blood and blood components for transfusion manufactured as part of the Health and Human Services National Blood Collection and Utilization Survey (NBCUS), which, historically, has a high response rate.<sup>1</sup>

## 2. Cell and Gene Therapy Products, Where One Lot Treats a Single Patient

In accordance with section 510(j)(3)(B) of the FD&C Act, FDA is proposing to exempt cell and gene therapy products, where one lot treats a single patient, from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution, is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Manufacturers of cell and gene therapy products, where one lot treats a single patient, maintain a highly controlled and secure supply chain from initial request for treatment of a patient to final product delivery to the site where the treatment occurs. This is because, due to the nature of these products, manufacturers implement strict chain of identity procedures to track products through the manufacturing process, to make sure the correct product gets to the correct patient. Additionally, the supply chains for these products are well-established and well-

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<sup>1</sup> See <https://doi.org/10.1111/trf.16449>. The response rate for the 2019 NBCUS was 94 percent for community-based blood collection facilities and 84 percent for hospital-based blood collection facilities.

understood from information described in the biologics license application (BLA), and generally do not involve wholesale distributors, brokers, or other intermediaries.

Additionally, pursuant to § 600.81 (21 CFR 600.81), the Agency generally receives lot distribution reports every 6 months from BLA holders. Specifically, reports submitted to the Agency under § 600.81 include, among other information, the fill lot numbers for the total number of dosage units of each strength or potency distributed, the label lot number (if different from fill lot number), the number of doses in fill lot/label lot, and the date of release of fill lot/label lot for distribution. For this category of biological products, since one lot treats a single patient, the lot distribution reports submitted to the Agency under § 600.81 represent the amount of product manufactured for commercial distribution, and additional reporting of such information under section 510(j)(3)(A) of the FD&C Act would be redundant.

### III. Paperwork Reduction Act of 1995

This proposed order contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). Information collection associated with section 510(j)(3) of the FD&C Act, requiring each person who registers with FDA with regard to a drug to report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution, is approved under OMB control number 0910-0045. If finalized, we believe the order will reduce burden associated with the approved information collection by exempting these biological product categories from such reporting requirements. We invite comment on our assumptions.

### IV. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 30 days after its date of publication in the *Federal Register*.

Dated: October 21, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021-23396 Filed: 10/26/2021 8:45 am; Publication Date: 10/27/2021]